



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0749]

Implanted Blood Access Devices for Hemodialysis; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Implanted Blood Access Devices for Hemodialysis.” This guidance was developed to support the reclassification of the Implanted Blood Access Devices for Hemodialysis into class II (special controls). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Implanted Blood Access Devices for Hemodialysis” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your

request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1540, Silver Spring, MD 20993, 301-796-6527.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document is being issued in conjunction with a Federal Register notice announcing the proposal to reclassify this device type. This draft guidance provides recommendations to assist manufacturers in developing their premarket submissions of implanted blood access devices for hemodialysis regulated under § 876.5540(a)(1) (21 CFR 876.5540(a)(1) and FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of implanted blood access devices for hemodialysis. Thus, a manufacturer who intends to market a device of this generic type must (1) Conform to the general controls of the Federal Food, Drug & Cosmetic Act (the FD&C Act), including the premarket notification requirements described in 21 CFR part 807 Subpart E, (2) address the special controls associated with implanted blood access devices for hemodialysis codified in the Code of Federal Regulations § 876.5540(b)(1), and (b)(3) obtain a substantial equivalence

determination from FDA prior to marketing the device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on implanted blood access devices for hemodialysis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "implanted blood access devices for hemodialysis" you may either send an e-mail request to ds mica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1781 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 820 have been

approved under OMB control number 0910-0073; the collections of information in 21 CFR part 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR § 56.115 have been approved under OMB control number 0910-0130; and the collections of information in 21 CFR part 54 have been approved under OMB control number 0910-0396.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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